IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

IN RE: AFLIBERCEPT PATENT LITIGATION	MDL No. 1-24-md-3103-TSK

THIS DOCUMENT RELATES TO:

Civil Action No. 1:23-cv-94-TSK

Civil Action No. 1:23-cv-106-TSK

STIPULATION AND ORDER TO SUPPLEMENT PRELIMINARY INJUNCTION RECORD

WHEREAS Regeneron Pharmaceuticals, Inc.'s ("Regeneron") Motion for Preliminary Injunction (ECF No. 118 in 1:23-cv-94; ECF No. 99 in 1:23-cv-106) ("PI Motion") was fully briefed as of April 18, 2024;

WHEREAS, on May 20, 2024, Samsung Bioepis, Co., Ltd. ("SB") received final approval from the Food and Drug Administration ("FDA") of its Biologics License Application ("BLA") No. 761350 for OPUVIZ™ (aflibercept-yszy) injection, 2 mg for intravitreal use in a single-dose vial and vial kit, as reflected in the approval letter attached as Exhibit A hereto;

IT IS THEREFORE STIPULATED AND AGREED that Exhibit A shall be part of the record for purposes of considering Regeneron's PI Motion.

SO ORDERED this 28th day of May 2024

Tom S Kleeh

THOMAS S. KLEEH, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA

Date: May 24, 2024

CAREY DOUGLAS KESSLER & RUBY, PLLC

/s/ David R. Pogue

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Date: May 24, 2024

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Attorneys for Defendant
Samsung Bioepis Co., Ltd.
appearing for the limited purpose of
contesting jurisdiction

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on the 24th day of May 2024, service of the foregoing document was made to counsel of record by CM/ECF filing.

/s/ Sandra K. Law
Sandra K. Law (WVSB No. 6071)

EXHIBIT A

U.S. FOOD & DRUG ADMINISTRATION

BLA 761350

BLA APPROVAL

Samsung Bioepis Co., Ltd.
c/o MMS Holdings, Inc.
Attention: Andrew Zelar, Ph.D.
U.S. Agent for Samsung Bioepis Co., Ltd.
6880 Commerce Boulevard
Canton, MI 48187

Dear Dr. Zelar:

Please refer to your biologics license application (BLA) dated and received February 17, 2023, and your amendments, submitted under section 351(k) of the Public Health Service (PHS) Act for Opuviz (aflibercept-yszy) injection.

We acknowledge receipt of your amendment dated March 6, 2024, which constituted a request for approval following our February 16, 2024, provisional determination letter. This BLA provides for Opuviz (aflibercept-yszy) injection, 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a single-dose vial and vial kit as interchangeable with US-licensed Eylea (aflibercept) injection, 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a single-dose vial kit and single-dose pre-filled syringe.

LICENSING

We have approved your BLA for Opuviz (aflibercept-yszy) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Opuviz under your existing Department of Health and Human Services U.S. License No. 2046. Opuviz is indicated for neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture aflibercept-yszy drug substance at Samsung Biologics Co., Ltd. in Incheon, Republic of Korea. The final formulated drug product will be manufactured and filled at (b) (4) . The filled drug product will be labeled and packaged at (b) (4) You may label your product with the proprietary name, Opuviz, and market it as 2 mg (0.05 mL of 40 mg/mL solution) in a single-dose vial and vial kit.

DATING PERIOD

The dating period for Opuviz shall be 30 months from the date of manufacture when stored at 5 ± 3 °C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be (b) (4) months from the date of manufacture when stored at (b) (4).

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Opuviz and each kit component to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of Opuviz, or in the manufacturing facilities, will require the submission of information to your BLA for our review and written approval, consistent with 21 CFR 601.12.

FIRST INTERCHANGEABLE EXCLUSIVITY

Section 351(k)(6) of the PHS Act provides:

> The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—
>
> (A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;
>
> (B) 18 months after—
>
> > (i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or
> >
> > (ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or
>
> (C)
>
> > (i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been

sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken and the term "first interchangeable biosimilar biological product" means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

Opuviz (aflibercept-yszy) injection, 2 mg (0.05 mL of 40mg/mL) for intravitreal use is the first product relying on its reference product to receive a determination of interchangeability for any condition of use. Therefore, with this approval, this product qualifies as a first interchangeable biosimilar biological product for purposes of section 351(k)(6) of the PHS Act. The expiration date of any first interchangeable exclusivity has yet to be determined.

For each interchangeable biosimilar biological product approved by this letter, submit a general correspondence to this 351(k) BLA informing the Agency of the date of the first commercial marketing within 30 days of such date. Submit a duplicate copy of the correspondence via email to PurpleBook@fda.hhs.gov.

If applicable, please submit a general correspondence to this 351(k) BLA informing the Agency of the date of any final court decision (as defined in section 351(k)(6) of the PHS Act) on all patents in suit in any action implicating this BLA instituted under section 351(l)(6) of the PHS Act, or the date of dismissal with or without prejudice of any action implicating this BLA instituted under section 351(l)(6), within 30 days of such date or within 30 days of this approval if such date occurred prior to approval. If any action implicating this BLA instituted under section 351(l)(6) is still ongoing at the time of this approval, submit a general correspondence informing the Agency of this within 30 days of this approval. Submit a duplicate copy of the correspondence(s) via email to PurpleBook@fda.hhs.gov.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As (October 2009)*.[2]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 761350**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4618-1 Conduct an in-use compatibility study to demonstrate the compatibility of SB15 vial drug product with the commercial vial kit components (syringe,

[1] See http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

filter needle, and injection needle) and any other administration components that may be used in lieu of the vial kit to prepare and administer a single dose of SB15.

The timetable you submitted on November 14, 2023, states that you will conduct this study according to the following schedule:

Final Report Submission: 11/2024

4618-2 Re-evaluate, and revise as appropriate, the drug substance and drug product specification limits (release and stability) for the purity and impurity tests (i.e., main species by non-reduced CE-SDS; main and LMW species by reduced CE-SDS; acidic, basic, and main species by icIEF; and monomer and HMW species by SE-HPLC) after one year of production where a sufficient number of lots are anticipated to be manufactured.

The timetable you submitted on November 22, 2024, states that you will conduct this study according to the following schedule:

Final Report Submission: 3/2026

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 21 CFR 600.80. Prominently identify all adverse experience reports as described in 21 CFR 600.80. You must submit distribution reports under the distribution reporting requirements at 21 CFR 600.81.

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[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Jacquelyn Smith, Senior Regulatory Health Project Manager, at jacquelyn.smith@fda.hhs.gov or 301-796-1002.

Sincerely,

{See appended electronic signature page}

Charles J. Ganley, M.D.
Director
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CHARLES J GANLEY
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